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May 12, 1993

TO: U.S. Nuclear Regulatory Commission ATTN: Document Control Desk Washington, D.C. 20555

RE:

NRC Bulletin 93-01: Release Of Patients After Brachytherapy Treatment With Remote Afterloading Devices

Pursuant to your letter of April 20, 1993, we have checked our QA procedures against the standards contained therein. As detailed below, we have found our procedures in complete accord with your guidelines.

The Northern Virginia Cancer Center installed a High Dose Remote After Loader (Microselectron HDR Ir192/ manufacturer Nucletron) in March-April 1991. The unit is located in a vault together with a linear accelerator Varian 6/100. At the time of installation the following radiation safety measures were designed and implemented:

A. HDR facility

 Since the HDR unit is located in the same room with the linear accelerator a switch was installed outside the treatment room to ensure independent functionality for each unit.

 The unit is connected to a master emergency stop switch located above the unit console. It is also connected to two other emergency stop switches: one located on the maze inside the treatment room, the other on the treatment unit head.

3. A positive door interlock monitors the door status, retracting the source as soon as the door is open.

4. Two independent warning lights (one for each unit) have been installed above the door signaling when the source is out of the safe or when radiation is emitted.

5. An area monitor (Nuclear Associate Primalert) with a remote Primalarm continuously monitors and visibly displays radiation presence. The monitor is equipped with a back up battery power supply and is checked for proper functionality twice a year with a Cs137 check source.

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Subsidiary of Alexandria Health Services Corporation

B. Users of the HDR unit

1. The use of the HDR unit is limited to physicians authorized for use of 10CFR 35.400 materials.

2. The HDR unit is operated exclusively by trained personnel:

- the initial training was provided by the "Nucletron" application specialists.

- training for new individuals is provided by the physicist

- retraining is conducted by the "Nucletron" Corporation annually or any time a modification or upgrading of the HDR unit takes place. The training records are kept in the department

C. Procedures for safety operation of the HER Unit

Each time before a procedure is scheduled the HDR unit is checked; The check covers:

- interlocks functions (door, "interrupt" key, emergency switch)

- correctness of the channel indexer

- accuracy of source position vs. position programmed

- integrity of the catheters and adapters.

- proper functionality of the survey meter (battery voltage and HV for the detector)

The findings are recorded in a daily QA log

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D. Treatment delivery

 During patient's treatment the physicist, the responsible physician, a radiation therapist trained in usage of the HDR and a nurse are present. No treatment was ever delivered without a physicist being present.

2. A system of audio-video monitors allows a constant communication with the patient.

3. At the end of the treatment each patient is surveyed using the survey meter designated exclusively for the HDR unit. The survey is recorded in our daily log book.

E. Emergency procedure

1. The emergency procedures cover the steps which must be taken in case the source does not retract and are posted at the HDR console; they are reviewed during training/retraining.

2. A large rectangular lead container (Radiation Products Design Inc.) kept inside the treatment room and with an inside dimension of 6"x6"x8" and 1" lead thick wall provides housing for all dimensions applicators in case the applicator needs to be taken out of the patient. It is to be noted that all catheters/applicators have a closed end.

3. The source cable and the applicators are handled using a long handle forceps placed by the patient during treatment delivery. A pair of surgical scissors is also available for cutting the tapes used for immobilization.

4. Before being assisted out of the treatment room, the patient is surveyed for possible radiation.

5. The room is closed and a "No Entry" sign placed on the door.

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cc: U.S. Nuclear Regulatory Commission Atlanta, GA

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